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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,969	02/16/2001	Bernard Charles Sherman	PT-1858001	3343

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EXAMINER	
KIM, VICKIE Y	
ART UNIT	**PAPER NUMBER**
1614	8

DATE MAILED: 03/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/783,969	SHERMAN, BERNARD CHARLES	
	Examiner	Art Unit	
	Vickie Kim	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 15-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 15-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1 and 15-21 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 19 recites the limitation "two surfactants" in claim 1 or 15. There is insufficient antecedent basis for this limitation in the claim because claim 15 only requires a surfactant.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 15, 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Hong et al(US 6063762).

The claims read on a composition comprising a micro emulsion preconcentrate including a cyclosporin dissolved in an acetylated monoglyceride lipophilic solvent, and a surfactant (e.g. polyoxyethylene-sorbitan-fatty ester). Claim 17 requires a fully acetylated monoglyceride. Claims 20-21 require an additional component that is a hydrophilic organic solvent(e.g. propylene carbonate, polyethylene glycol(less than 1000MW) .

Hong et al teach all the critical elements required by the instant claims. Hong teaches a microemulsion formulation comprising cyclosporin, lipophilic solvent(e.g. Mivacet 9-40. As applicant admitted in the instant specification(see page 3, lines 5-7 and page 7, lines 12-14), the emulsion with the droplet size than 2000 A are defined as "microemulsion" and fully acetylated monoglycerides are currently available under the designations "Mivacet 9-40". Thus Hong's micro-emulsion preconcentrate formulation including cyclosporin and lipophilic solvent (i.e. "Mivacet 9-40") meet the claims inherently.

Thus the claims are anticipated and not patentably distinct over the prior art of the record.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woo (US5589455) or Kim et al (US 5980939) in view of Hong et al (6,063,762).

Woo or Kim teaches a micro-emulsion preconcentrate composition comprising (1)cyclosporin; (2) hydrophilic co-surfactant(e.g. polyethylene glycol 200-600(MW) or propylene carbonate; (3) oil component (e.g. MIGLYOL-812) (4) surfactant(s)-(mixture of more than one surfactant is required in micro-emulsion preconcentrate); see claims and examples in each patent disclosure. As each patentee states, hydrophilic co-surfactant is also used as hydrophilic solvent for cyclosporin (see US'455, column 5, lines 19-20). Applicant also admits this inherently possessed features in the instant disclosure (see page 8, lines 19-21), wherein applicant defines that hydrophilic solvent is selected from propylene carbonate or polyethylene glycol (less than 1000MW).

Applicants claims differ because they require fully acetylated monoglycerides as an oil component.

However it would have been obvious to one of ordinary skill in the art to substitute oil component aforesaid in the cited references(Woo or Kim) with fully acetylated monoglyceride when Woo or Kim is modified with Hong et al (US 6028067 or 6063762) because Hong teaches the oil component could be chosen from extended selection including Miglyol-812 or Mivacet 9-40.

One would have been motivated to make such modification to extend the selection option for convenience and other benefits due to its mass production available

in commercial product(e.g. easy accessibility, obtainability, cost effectiveness), with reasonable expectation of success, because the utility of oil component in these patented compositions are same wherein one would achieves highly stable but superior solubilizing effect to the active ingredient, in addition to the fact that the same inventors(see inventors US 5980939 vs 6028067) are teaching this substitution. Therefore aforesaid substitution (i.e. Mivacet 9-40 to Miglyol 812) would be well within the skilled level of artisan and thus the claimed subject matter is not patentably distinct over the prior art of the record. Some critical elements required in preamble of dependent claims are also met because of the same reasons mentioned in 102 rejection(see immediate above 102 rejection, explanation for inherent features such as 2000A, Mivacet 9-40).

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities, and pertinent to the problem which applicant is concerning. MPEP 2141.01(a).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 15, 17-19 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. US 6258783. Although the conflicting claims are not identical, they are not patentably distinct from each other because the tem "microemulsion" limits the size of droplet. Thus the claimed subject matter is inherently encompassed by the patented claims and the broadly drafted instant claims include narrow defined claims(composition claimed) wherein the patented claims use the narrow descriptive -language "consisiting essentially".

Conclusion

11. All the pending claims are rejected.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Tuesday-Friday: 8AM-6:30PM).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
March 21, 2002

William Jarvis
Primary examiner
Art unit 1614